



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,525	11/29/2001	Erlinda M. Gordon	EPE1110-1	6086

20985 7590 07/28/2005

FISH & RICHARDSON, PC
12390 EL CAMINO REAL
SAN DIEGO, CA 92130-2081

EXAMINER

MONTANARI, DAVID A

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,525

Applicant(s)

GORDON ET AL.

Examiner

David Montanari

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, and 9-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 28th, 2005 has been entered.
2. Claims 1, 3, and 9-10 are examined in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, and 9-10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (WO 98/44938, 15 October 1998).

With regard to the 102(b) rejection filed on 12/28/2004 applicants argue that the ammendment to claim 1 "and wherein the cells of the tumor transduced by the vector express GM-CSF, resulting in the recruitment of host mononuclear cells to the site of the tumor", provides a limitation not anticipated by the art presented in the 102(b) rejection. This is not persausive. Hall et al. teaches a retroviral particle wherein the viral surface protein has been modified to include a targeting polypeptide that binds to an extracellular matrix component of a cell (including collagen) and the particle also comprises a therapeutic gene (including GM-CSF),

Art Unit: 1632

and a method of delivering therapeutic genes to a tumor and a method of treatment. The recruitment of host mononuclear cells to the site of the tumor is inherent to the retroviral particle taught by Hall et al. and clearly anticipates the invention of claims 1, 3, and 9-10. The retroviral particle taught by Hall et al. would result in the recruitment of host mononuclear cells to the site of the tumor since it is identical to the claimed targeted retroviral particle of the instant application. Applicants do not provide any evidence as to how the vector used by Hall et al. (WO 98/44938, 15 October 1998), that is the same vector as claimed instantly will not have the functional characteristics claimed instantly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, and 9-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al (WO 98/44938, 15 October 1998), or Hall et al. (Human Gene Therapy 11: 983-993, 2000), or Liu et al (J. of Virology 74: 5320-5328, 2000), Gordon et al (Cancer Res. 60: 3343-3347, 2000), in view of Kurane et al (Annals of Surgery 4: 579-585, 1997) and Borello et al (Human Gene Therapy 10: 1983-1991, 1999) for reasons of record set forth in the previous office actions of 8/21/03, 5/18/04 and 4/4/2005.

With regard to the 103 rejection applicant argues that the addition of the limitation "and wherein the cells of the tumor transduced by the vector express GM-CSF, resulting in the

Art Unit: 1632

recruitment of host mononuclear cells to the site of the tumor" to claim 1 renders the claimed invention unobvious to the art provided in the rejection filed 12/28/2004. This is not persuasive. The references Hall et al., Hall et al., Gordon et al., Kurane et al., and Borello et al. for reasons of record already presented in the office action filed 08/21/2003 also obviate the claimed invention. Applicants do not provide any evidence as to how the vector used by Hall et al. (WO 98/44938, 15 October 1998), or Hall et al. (Human Gene Therapy 11: 983-993, 2000), or Liu et al. (J. of Virology 74: 5320-5328, 2000), Gordon et al. (Cancer Res. 60: 3343-3347, 2000), in view of Kurane. et al (Annals of Surgery 4: 579-585, 1997) and Borello et al. (Human Gene Therapy 10: 1983-1991, 1999) that is the same vector as claimed instantly will not have the functional characteristics claimed instantly.

No claims are allowed.

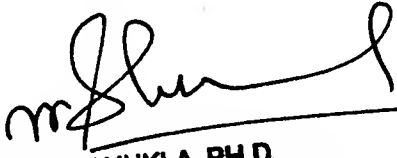
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 1-571-273-8300.

Art Unit: 1632

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Montanari, Ph.D


RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER